

Decree of the Chairman of the Egyptian Drug Authority No. (157) of 2026

Chairman of Egyptian Drug Authority,

Having perused

- Law No. 127 of 1955 on the Practice of Pharmacy;
- Law No. 151 of 2019 on the Establishment of the Egyptian Drug Authority;
- The minutes of the meeting of the Board of Directors of the Authority at its session held on 20/7/2020;
- Based on the Decree of the Chairman of the Egyptian Drug Authority No. 343 of 2021 regarding the rules for registering biological products;
- Presidential Decree No. (28) of 2026 forming the Board of Directors of the Egyptian Drug Authority;
- Based on the submission of the Head of the Central Administration for Biological and Innovative products and Clinical studies;
- And in the interest of work;

Decides

(Article One)

The provisions of this Decree shall apply with respect to implementation of the reliance system on regulatory health authorities in all regulatory functions related to imported biotherapeutics, including marketing authorization , laboratory testing, lot release, clinical trials, and inspection(, provided that such products have obtained a valid marketing authorization License from one of the reference countries accredited by the Technical Committee for Drug Control.

(Article Two)

The Head of the Central Administration for Biological , Innovative products and Clinical studies shall issue the Regulatory Guideline governing the implementation of the reliance system on regulatory health authorities in respect of all regulatory functions applicable to imported biotherapeutics that have obtained a valid marketing authorization License from one of the approved Reference Regulatory Authorities.

(Article Three)

This Decision shall enter into force as of the date of its issuance. All competent departments shall implement this Decision, each within the scope of its respective jurisdiction.

Dr.Ali El-Ghamrawy

Chairman of the Egyptian Drug Authority

Written on: 1/4/2026